

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

OCT 20 2009

David B. Quick ICE MILLER LLP One American Square Suite 2900 Indianapolis, IN 46282-0200

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,919,140

Dear Mr. Quick:

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,919,140 for a period of 1 year. A copy of the Federal Register notice published in accordance with 35 U.S.C. 156(d)(5)(B) on October 16, 2009 at 74 Fed. Reg. 53217 is enclosed herewith. While a courtesy copy of this letter and the interim extension is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail to mary.till@uspto.gov.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

cc:

Office of Regulatory Policy Food and Drug Administration 10903 New Hampshire Ave., Bldg. 51, Rm. 6222 Silver Spring, MD 20993-0002 RE: AndaraTM OFSTM System FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Purdue Research Foundation Request for Patent Term Extension

U.S. Patent No. 4,919,140

ORDER GRANTING

INTERIM EXTENSION

On September 11, 2009, the patent owner, Purdue Research Foundation, timely filed a second application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,919,140. The patent claims the medical device known as AndaraTM OFSTM System and a method of using the AndaraTM OFSTM System. The application indicates that a Humanitarian Device Exemption, HDE 070002, for the medical device AndaraTM OFSTM System has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (October 14, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

A second interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,919,140 is granted for a period of one year from the expiration date of the patent, i.e., until October 14, 2010.

Date(

David J. Kappos

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office